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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,589	06/24/2003	Lawrence Shih Hsin Wu	MR2707-36	8444

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EXAMINER

SCHEINER, LAURIE A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/601,589

Applicant(s)

WU ET AL

Examiner

Laurie A. Scheiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/24/03 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

Claims 1-14 are objected to because of the following informalities: STR as recited should read as "short tandem repeats" in all claims. Alternatively, applicants may choose to amend claim 1 only by replacing STR with "short tandem repeat (STR)." Also, "an" in line 1, of claim 1, should be replaced by --a--. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The basis for this rejection is set forth in the two-step test given by In re Freeman 197 USPQ 464 (CCPA 1980), as modified by In re Walter 205 USPQ 397 (CCPA 1982), and In re Abele 214 USPQ 682 (CCPA 1982), see In re Meyer 215 USPQ 193, 198 (CCPA 1982).

The first step of determining the Freeman-Walter-Abele test is to determine whether or not the claims recite a mathematical algorithm. Claim 1 recites the following steps:

[i)] STR genotyping; [ii)] associating significant STR markers with response of interferon treatment by Monte-Carlo estimation; [iii)] testing alleles on significant STR markers; [iv)] transferring significant alleles to genotype information; and [v)] generating an equation. Dependent claims add the further steps of amplifying STR markers fragments, and detecting and analyzing STR polymorphism; obtaining loci correlated with drug response; analyzing a contingency table; constructing a genotype contingency table; transferring genotype information to a binary dataset; practicing a logistic regression; allele frequency difference testing; genotype frequency difference testing; selecting a plurality of STR markers to form a combination for generating an equation; and, estimating an error rate for a first combination.

Thus, the claims clearly recite mathematical algorithms, i.e. "Monte-Carlo estimation", "transferring . . . information", "generating an equation", "associating", "correlated", "analyzing a contingency table", transferring . . . information to a binary dataset", etc.

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The next step is to determine whether or not the claim, as a whole, preempts the algorithm. See In re Abele 214 USPQ 682, 685 (CCPA 1982); In re Iwahashi 12 USPQ 2d 1908, 1911 (CAFC) 1989; and In re Grams 12 USPQ 2d 1824, 1827 (CAFC) 1989. In order to make this determination, the claims are viewed without the mathematical algorithm to determine if what remains is otherwise statutory. See In re Abele 214 USPQ 682, 686 and In re Grams 12 USPQ 2d 1824, 1827. Limitations that have been determined not to provide a statutory basis for claims include post-solution activity, field of use limitations, and data-gathering steps. The courts have held that any non-essential "post-solution" activity fails to render the claims statutory. See Parker v. Flook 198 USPQ 193, 197 (S. CT 1978). The Court has held that a field of use limitation cannot make a claim statutory by "attempting to limit the use of the formula to a particular technological environment" Diamond v. Diehr 209 USPQ 1,10 (S. CT 1981).

With regard to data gathering steps, the courts have held that:

"No mathematical equation can be used, as a practical matter, without establishing and substituting values for the variables expressed therein. Substitution of values dictated by the formula has thus been viewed as a form of mathematical step. If the steps of gathering and substituting values were alone sufficient, every mathematical equation, formula, or algorithm having any practical use would be per se subject to patenting as a "process" under 101. Consideration of whether the substitution of specific values is enough to convert the disembodied ideas present in the formula into an embodiment of those ideas, or into an application of the formula, is foreclosed by the current state of the law." In re Sarker 200 USPQ 132, 139 (CCPA 1978).

Steps which "merely determine values for the variables used in the mathematical formulae used in making the calculations...do not suffice to render the claimed methods, considered as a whole, statutory subject matter." In re Richman, 563 F.2d at 1030, 195 USPQ at 343.

"The presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory." In re Grams 12 USPQ 2d 1824, 1828.

Rewriting claim 1 without the mathematical steps leaves the following:

"A modeling method for predicting an hepatitis B patient to response to interferon treatment, comprising the steps of: [i)] STR genotyping." Clearly, without the algorithm, claim 1 recites merely a data-gathering step. The data collection step is needed to generate the unknown algorithm which functions in the invention as the model, yet values (data) cannot be applied since a formula has not been derived. The algorithm to which the claims are drawn has

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not been set forth since it must first be generated from the data to be collected. In short, the invention as claimed is drawn to obtaining data to generate an algorithm.

Claims 13 and 14, although drafted independently from claim 1, merely recite a model comprising a plurality of STR markers (5 STR markers) and an equation. That is, the unknown algorithm as the model, resulting from the method of making the model.

Thus, when taken as a whole, the claims are directed to algorithms and do not define patentable subject matter which preempt the algorithms.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility.

The method as disclosed and claimed presents a research plan to identify small tandem repeat polymorphisms which, when used in an algorithm, may be a model predictive of a particular chemotherapy response. However, extensive random unpredictable experimentation is left for others to identify which polymorphisms are, and which are not, relevant and to thereby generate an unknown algorithm which functions in the invention as the model. The modeling method itself, obtaining data to generate an algorithm, does not produce any concrete, tangible, or useful result and therefore lacks utility.

#### ***Status of the Claims***

Currently, no claims are allowable.

#### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-

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0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Laurie Scheiner/LAS  
March 16, 2005



Laurie Scheiner  
Primary Examiner  
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